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Filing Date	3/4/2002
First Named Inventor	Juan I. Perez
Art Unit	3738
Examiner Name	Thomas C. Barrett
Total Number of Pages in This Submission: 15	Attorney Docket Number: ENDOV-55674

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
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- ☐ Proprietary Information
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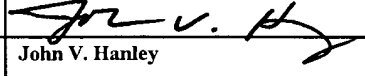
Signature			
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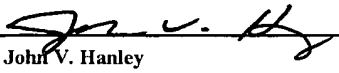
Signature			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of	Examiner: Thomas Barrett
Inventor: Juan I. Perez, et al.	Group Art Unit: 3738
Serial No. 10/091,172	
Filed: March 4, 2002	Date: October 9, 2006
For: STAGED ENDOVASCULAR GRAFT DELIVERY SYSTEM	

SECOND SUPPLEMENTAL APPELLANT'S BRIEF (CFR § 1.192)

MS: Appeal Brief Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Second Supplemental Appellant's Brief is being filed in response to the Notification of Non-Compliant Appeal Brief dated October 3, 2006, as well as in response to the September 6, 2006 Office communication and the final Office action dated January 31, 2006. The fees required under § 1.17 were submitted on May 1, 2006 with the Notice of Appeal. The fee associated with this paper was filed on June 20, 2006. In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

This brief contains items under the following headings, and in the order set forth below:

I. REAL PARTY IN INTEREST

II. RELATED APPEALS AND INTERFERENCES

III. STATUS OF CLAIMS

IV. STATUS OF AMENDMENTS

V. SUMMARY OF CLAIMED SUBJECT MATTER

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

VII. ARGUMENT

VIII. CLAIMS APPENDIX

IX. EVIDENCE APPENDIX

X. RELATED PROCEEDINGS APPENDIX

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Guidant Corporation which is a wholly-owned subsidiary of Boston Scientific Corporation, 1 Boston Scientific Place, Natick, MA 01760.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 1-25

B. Status of All of the Claims

Each of pending claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 stand as finally rejected under 35 U.S.C. § 102(b). Additionally, claims 1-10, 12-22, 24 and 25 stand as finally rejected under § 103(a). Claims 11 and 23 were objected to as being dependent upon a rejected claim.

C. Claims on Appeals

The claims on appeal are each of pending claims 1-10, 12-22, 24 and 25.

IV. STATUS OF AMENDMENTS

No amendments to the claims were filed subsequent to the issuance of the January 31, 2006 final Office action.

In the January 31, 2006 final Office action, claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Poncet (U.S. 5,833,694; Exhibit A). Additionally, claims 1-9, 12-22, 24 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. (U.S. 6,090,136; Exhibit B) in view of Staehle et al. (U.S. 6,132,458; Exhibit C). Claim 10 was rejected under § 103(a) in view of Poncet.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claims 1 and 18, the presently claimed invention relates to a system including a sheath assembly and a loading capsule (See Summary of the Invention, page 7, line 5 et seq.). An initial or a first treatment component in the form of

an implant or a graft 120 as well as subsequent treatment components in the form of implants or graft components 128 are received by the system and advanced thereby to a treatment site (See also original claims 1 and 18; See page 19, line 3 et seq. and FIGS. 1-1E). In one particular aspect, the system 110 includes a loading capsule 112 having a superior end that is configured to mate with an inferior end of the introducer sheath 111, (See page 20, line 10 et seq.). As specifically required by claim 18, a pusher assembly 113 is further provided to releasably receive a plurality of graft components (See page 19, line 20 et seq.). In this way, a system that accomplishes delivering initial and then successive treatment components to a treatment site is provided.

As set forth in independent method claim 22, the presently claimed invention relates to a process for treating vasculature which involves employing a system including a sheath assembly and a loading capsule (See Summary of the Invention, page 7, line 5 et seq.). An initial or a first treatment component in the form of an implant or a graft 120 as well as subsequent treatment components in the form of implants or graft components 128 are received by the system and advanced thereby to a treatment site (See also original claim 22; See page 19, line 3 et seq. and FIGS. 1-1E). The method includes gaining access to vasculature, inserting an initial introducer sheath 111 loaded with a graft component within vasculature and positioning a lead end of the sheath at the repair site. Thereafter, the initial introducer sheath is retracted to deploy the graft component (See page 19, line 10 et seq.; See original claim 22). A superior end of the loading capsule 112 is mated to an inferior end of the sheath 111 and a subsequent graft component 128 is advanced within the sheath 111 (See page 19, line 20 et seq. and page 21, line 10 et seq.). The subsequent component 128 is then deployed at the repair site (See page 22, line 1 et seq.).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 were improperly rejected under 35 U.S.C. § 102(b) as being anticipated by Poncet. Additionally, whether claims 1-9, 12-22, 24 and 25 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonald et al. in view of Staehle et al. and whether claim 10 was improperly rejected under § 103(a) in view of Poncet.

VII. ARGUMENT

A. § 102(b) Rejection

As stated, claims 1-6, 8, 9, 12, 15, 17-19, 21, 24 and 25 were rejected under § 102(b) as being anticipated by Poncet. It is respectfully submitted, however, that Poncet does not teach each and every limitation recited in the rejected claims as is required under 35 U.S.C. § 102(b).

In rejecting the claims in view of the Poncet reference, the Examiner drew the Applicants attention to Col. 8, lns. 4-15 and figures 12 and 13 of that reference. However, these sections of the Poncet patent upon which the Examiner relies does not teach the combination of the first sheath and the loading capsule recited in the pending claims.

Each of independent claims 1 and 18 recite a system including a loading capsule including a superior end and a sheath including an inferior end, the superior and inferior ends being configured to mate with each other. The terms superior and inferior are defined in the present application at page 8, line 12 et seq. Significantly, FIGS. 12 and 13 of Poncet disclose a sheath 10 including an enlarged portion 16 at its distal or superior end. Stents are loaded into distal or superior end of the sheath 10 by employing a stent cartridge 130 with an open end 134 formed at its superior or distal end and which is designed to mate with the enlarged portion 16 of the sheath 10.

Accordingly, rather than teaching the recited loading capsule with a superior end that mates with an inferior end of a sheath, the Poncet reference actually teaches mating superior ends of two devices. This difference is significant since one intent of the present invention is to provide a sheath which includes a superior end which remains in vasculature while subsequent treatment devices are inserted within the inferior end of the sheath to subsequently be advanced through the sheath to its superior end.

Therefore, it is submitted that the Poncet patent does not teach each and every limitation recited in independent claims 1 and 18 or their respective dependent claims, namely claims 2-6, 8, 9, 12, 15, 17, 24 and claims 19, 21 and 25. As such, it is respectfully submitted that these claims were improperly rejected under § 102(b).

B. § 103(a) Rejection

Claims 1-9, 12, 22, 24 and 25 were rejected under § 103(a) over McDonald et al. in view of Staehle et al. and claim 10 was rejected under § 103(a) over Poncet.

It is respectfully submitted, however, that none of the cited prior art references teach the subject matter recited in independent claims 1, 18 and 22 or their respective dependent claims. Significantly, none of the cited art, either alone or in combination, teach a system including a first sheath configured to receive a subsequent treatment or graft component after the sheath is placed within vasculature and a loading capsule including a superior end that is configured to mate with an inferior end of the first sheath.

A tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

It is also significant to the present application that MPEP 2145 states that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine references teachings. It is additionally to be noted that MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination" and that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because references relied upon teach all of the aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facia* case of obviousness without some objection reason to combine the teachings of the references." Further, the MPEP states that "The level of skill in the art cannot be relied upon to provide the suggestion to combine the references."

In rejecting the claims under § 103(a) over McDonald et al. in view of Staehle et al., the Examiner stated that "It would have been obvious to one of ordinary skill in the art to combine the teachings...the motivation to combine being the capsule of Staehle et al. is an 'easy and effective loading device' " (Col. 2, lines 24-26). It is respectfully submitted, however, that the motivation upon which the Examiner has relied to combine the teachings does not satisfy the guidelines provided by the MPEP as set forth above.

That is, simply because the Staehle et al. patent states that there is a need for "an effective loading device" (which, incidentally, is a statement made in the Background of the Invention of Staehle et al. and one which is not made respecting nor necessarily attributable to the Staehle et al. disclosed device) does not support modifying the teachings of McDonald et al. as suggested by the Examiner. Significantly, the device 10 of Staehle et al. includes a funnel 19 intended to

reduce the profile of a stent while advancing the stent within a deployment tool 12. However, there is nothing in the cited references to suggest that such an approach would even be workable with the rolled stent 13 disclosed in McDonald et al. In fact, one can imagine the rolled stent 13 of McDonald et al. becoming stuck within the funnel 19 structure of the Staehle et al. device 10 if an attempt was made to advance it therethrough. Accordingly, it is submitted that there is no basis for concluding that one of ordinary skill in the art would have modified the approach taught by McDonald et al. to include the device 10 of Staehle et al. Thus, it is respectfully submitted that a sufficient objection reason has not been provided to combine the teachings of McDonald et al. and Staehle et al. and as such, a *prima facia* case of obviousness has not been established to reject the claims.

Moreover, even if the combination was proper under the MPEP, it is significant that both the McDonald et al. and the Staehle et al. references are lacking in the teaching of the recited sheath and loading capsule. That is, the cited references also do not meet the limitations of independent apparatus claims 1 and 18 or independent method claim 22 which require among other things, mating or a mating arrangement between a superior terminal end of a loading capsule with an inferior end of sheath.

As the Examiner noted, the McDonald et al. patent does not teach the recited loading capsule. Moreover, as established above, there is no suggestion or teaching that the Staehle et al. structure would work with the McDonald et al. stent. Further, there is no indication in Staehle et al. that the disclosed structure it is intended to include a superior end configured to mate with an inferior end of a sheath. Therefore, the combination of McDonald et al. and Staehle et al. fail to meet the limitations recited in claims 1-9, 12-22, 24 and 25.

Also, as set forth above in the section concerning the § 102 rejection, the Poncet patent completely lacks the teaching of a mating arrangement between a superior end of a loading capsule and an inferior end of a sheath. Thus, the § 103(a) rejection of claim 10 over Poncet necessarily must fall short since claim 10 further limits claim 1.

Accordingly, it is submitted that the § 103(a) rejections of the claim 10 as well as claims 1-9, 12-22, 24 and 25 were improper.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the Examiner has erred in rejecting claims 1-10, 12-22, 24 and 25. It is respectfully requested that the Board reverse the rejection of the claims 1-10, 12-22, 24 and 25 and pass each of pending claims 1-25 to issue.

Respectfully submitted,

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VIII. CLAIMS

Claim 1 (previously presented): A system for treating vasculature at a repair site, comprising:

a first treatment component;

a first sheath having the first treatment component and configured to receive a subsequent treatment component after the first sheath is placed within the vasculature and the first treatment component is deployed, the first sheath having an inferior end and a length sufficient to extend to a repair site within the vasculature; and

a loading capsule configured to receive a subsequent treatment component, wherein the loading capsule includes a superior terminal end that is configured to mate with the inferior end of the first sheath.

Claim 2 (previously presented): The system of claim 1, further comprising a plurality of subsequent treatment components.

Claim 3 (previously presented): The system of claim 2, wherein the initial sheath is retracted to deploy treatment components at a repair site.

Claim 4 (previously presented): The system of claim 2, wherein the first sheath is configured to retain the plurality of subsequent treatment components in a compressed configuration.

Claim 5 (previously presented): The system of claim 1, wherein the first treatment component is self-expanding.

Claim 6 (previously presented): The system of claim 5, wherein the loading capsule is configured to releasably retain the first treatment component in a compressed configuration.

Claim 7 (previously presented): The system of claim 1, further comprising a guidewire.

Claim 8 (previously presented): The system of claim 1, further comprising a pusher assembly.

Claim 9 (previously presented): The system of claim 8, wherein the pusher assembly is configured to simultaneously engage a plurality of treatment components.

Claim 10 (previously presented): The system of claim 8, the pusher assembly further comprising a tapered flexible tip.

Claim 12 (previously presented): The system of claim 8, the pusher assembly includes an inner tube.

Claim 13 (previously presented): The system of claim 12, the inner tube including an inferior end, a superior end and an exit notch.

Claim 14 (previously presented): The system of claim 13, the inner tube further comprising a guidewire passageway between the superior end and exit notch.

Claim 15 (previously presented): The system of claim 1, wherein the loading capsule and first sheath have approximately equal outer profiles at a mating juncture therebetween.

Claim 16 (previously presented): The system of claim 8, wherein the pusher assembly is configured to advance treatment components substantially the length of the first sheath.

Claim 17(previously presented): The system of claim 1, wherein the first sheath remains within vasculature during the delivery of multiple treatment components at a repair site.

Claim 18 (previously presented): A system for treating vasculature at a repair site, comprising:

a plurality of endovascular graft components;

a pusher assembly configured to releasably receive each of the plurality of endovascular graft components;

a loading capsule assembly configured to receive the pusher assembly and including a superior terminal end; and

an introducer sheath having an inferior end configured to mate with the superior terminal end of the loading capsule assembly and to facilitate the transfer of the plurality of endovascular graft components from the loading capsule assembly.

Claim 19 (previously presented): The system of claim 18, wherein the introducer sheath and the loading capsule have substantially the same outer profiles at a mating juncture therebetween.

Claim 20 (previously presented): The system of claim 18, further comprising a guidewire.

Claim 21 (previously presented): The system of claim 18, wherein each of the plurality of endovascular grafts are self-expanding.

Claim 22 (previously presented): A method for treating vasculature at a repair site using a system including an initial introducer sheath having an inferior end and configured to receive an endovascular graft and configured to receive subsequent endovascular graft components carried by a loading capsule with a superior terminal end after placement of the introducer sheath within vasculature, the introducer sheath extending to the repair site, comprising:

gaining access to vasculature;

inserting initial introducer sheath loaded with the endovascular graft component within vasculature and positioning a superior end of the initial introducer sheath at the repair site;

retracting the initial introducer sheath to deploy the endovascular graft component;

mating the superior terminal end of the loading capsule with the inferior end of the initial introducer sheath;

inserting a subsequent endovascular graft component in the inferior end of the initial introducer sheath;

advancing the subsequent endovascular graft component within the initial introducer sheath; and

deploying the subsequent endovascular graft component at the repair site by retracting the initial introducer sheath.

Claim 24 (previously presented): The system of claim 1, further comprising:

a first fitting, the first fitting attached to the superior terminal end of the loading capsule; and

a second fitting, the second fitting attached to the inferior end of the first sheath;

wherein the first fitting and second fitting releasably connect to each other.

Claim 25 (previously presented): The system of claim 18, further comprising:

a first fitting, the first fitting attached to the superior terminal end of the loading capsule; and

a second fitting, the second fitting attached to the inferior end of the first sheath;

wherein the first fitting and second fitting releasably connect to each other.

IX. EVIDENCE APPENDIX

NONE

X. RELATED PROCEEDINGS APPENDIX

NONE